

Certificate of Analysis

Product name: **Isosorbidi dinitras dilutus**

Batch number / Weight: **22D11-B05-216313 / 5 G**

Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification C	Conform	Conform		
Identification D	69 - 72	71,4	°C	
Impurity A	<=0,5	<0,5	%	
Impurities B and C	<=0,5% each	0,05/0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Isosorbide dinitrate	38,0 - 42,0	39,74	%m/m	
Assay	95,0-105,0 stated on label	99,11	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Acetone	<=5000	<5000	ppm	

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

08-07-2022

Expiration: 11-03-2027

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.